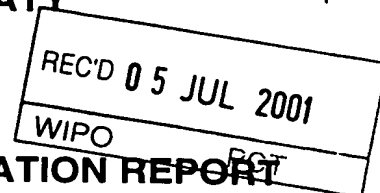


PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference OFX042BWO	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP00/02953	International filing date (day/month/year) 03/04/2000	Priority date (day/month/year) 08/04/1999
International Patent Classification (IPC) or national classification and IPC A61B17/86		
Applicant ORTHOFIX SRL		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 5 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 23/10/2000	Date of completion of this report 03.07.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Valfort, C Telephone No. +49 89 2399 2352 

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP00/02953

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):
Description, pages:

1-6 as originally filed

Claims, No.:

1-10 as originally filed

Drawings, sheets:

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.
4. The amendments have resulted in the cancellation of:
- ☐ the description, pages:
- ☐ the claims, Nos.:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-10
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-10
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-10
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/EP00/02953

1. Reference is made to the following documents:

D1: US-A-4 463 753 (GUSTILO) 7 August 1984 (1984-08-07)

D2: EP-A-0 012 441 (EBERHARD JAEGER GMBH & CO. KG) 25 June 1980 (1980-06-25)

D3: DE 43 29 788 A (MAUK ET AL.) 9 March 1995 (1995-03-09)

Re Item V

2. D1 discloses a bone screw suitable for use in orthopaedic surgery, which comprises a head (11, fig.2), a shank (3, fig.2), and a threaded portion (2, fig.2) tapering towards a tip (see fig.2) at the opposite end from the end (11, fig.2) wherein said threaded portion (tapering towards the tip) has at least one constant pitch section (see col.5 lines 6-7) section comprising threads with an acute angle (see col.5 lines 32-54) or cusp-like triangular profile in cross section (see fig.2).
- 2.1 Document D1, which is considered to represent the most relevant state of the art, discloses (cf. 3) a bone screw from which the subject-matter of claim 1 differs in that said threads of threaded portion tapering towards the tip are separated from each other by a shaped bottom land having a concave profile defined by two countersloping planes.
- 2.2 The special shape used between the threads ease the material flow and relieves bone stress during the screw penetration (see page 4 of the description lines 15-17).
- 2.3 The problem to be solved by the present invention may therefore be regarded as how to modify the screw of D1 so as to obtain the effect cited in point 3.2.
- 2.4 The special shape of the thread is known in document D2 (see fig.2, and page 7 lines 2-11) and provide the same effects (see page 8 lines 22-25), but this shape is used on the portion of the shaft of the screw which is not tapering to the tip, the threads on the portion tapering to the tip are separated by straight portions (see fig.3), therefore it appears not be obvious to the person skilled in the art wishing to solve the precedent problem, to apply the special countersloping planes on the tapering portion of the screw of D1. Thus, the subject-matter of claim 1 do not appear to be obvious

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/EP00/02953

in view of the cited documents. In D3, the screw does not have countersloping planes between the threads but concave round portions (fig.1), or direct straight threads (56, fig.55).

3. Claims 2-10 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Re Item VII

4. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Re Item VIII

5. The terms "improved" and "of the type" in claim 1 and "about" in claim 8 are unclear and leave the reader in doubt so as to the subject-matter for which protection is sought (Article 6 PCT and PCT guidelines III.4.5a and III.4.6).

INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 00/02953

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/86

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B F16B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 463 753 A (GUSTILO) 7 August 1984 (1984-08-07) abstract; figures 1-4 column 2, line 36 -column 3, line 11 ---	1-5,8-10
Y	DE 43 29 788 A (MAUK ET AL.) 9 March 1995 (1995-03-09) the whole document ---	1-5,8-10
A	FR 1 266 386 A (MUELLER) 10 November 1961 (1961-11-10) the whole document ---	1-5
A	US 5 505 736 A (REIMELS ET AL.) 9 April 1996 (1996-04-09) abstract; figures ---	1-5
-/--		

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

23 June 2000

Date of mailing of the international search report

29/06/2000

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 00/02953

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3 915 162 A (MILLER) 28 October 1975 (1975-10-28) abstract; figures column 2, line 23-28 ----	1
A	EP 0 012 441 A (EBERHARD JAEGER GMBH & CO. KG) 25 June 1980 (1980-06-25) page 7, line 2 -page 8, line 25; figure 2 -----	1-7

INTERNATIONAL SEARCH REPORT

Interr. .nal Application No

PCT/EP 00/02953

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 4463753	A	07-08-1984	CA	1162124 A	14-02-1984
DE 4329788	A	09-03-1995	NONE		
FR 1266386	A	10-11-1961	NONE		
US 5505736	A	09-04-1996	NONE		
US 3915162	A	28-10-1975	NONE		
EP 0012441	A	25-06-1980	DE	2853976 A	19-06-1980
			DE	2948595 A	11-06-1981